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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,949	03/22/2004	Gary D. Niehaus	25080/04026	9888
24024	7590	05/17/2005	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/805,949

Applicant(s)

NIEHAUS, GARY D.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 23-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-22, in the reply filed on 15 March 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 23-40 have been withdrawn from consideration as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague because it recites "low birefringent glass" and it is unclear what is encompassed by low. It is vague as to how much birefringent is required in order to be considered low birefringent glass. Furthermore, it is unclear whether the "at least one mixing chamber" recited in line 4 of the claim is the same mixing chamber as "the one or more mixing chambers" in line 7 of the claim. Claim 1 recites the limitation "the outlet port" in line 7 of the claim. There is insufficient antecedent basis for this limitation in the claim.

With respect to claim 3, it is unclear whether the first and second conduit are within the flow channel recited in claim 1 or whether the flow channel is divided up into first and second conduits.

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Claim 4 recites the limitation "the first mixing chamber" in line 2 of the claim and "the last mixing chamber" in line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Regarding claim 5, it is unclear whether the two or more conduits are included in the flow channel recited in claim 1 or whether conduits are the sections of the flow channel between the chambers and ports. Furthermore, it is vague as to whether one conduit is arranged in series with the inlet port, mixing chambers and detection chamber or whether one conduit is used between each of the elements contained in the device. It is also unclear whether in line 3 of the claim "a conduit" refers to one of the two or more conduits or another, separate conduit and whether the "a conduit" is between each of the inlet port and a mixing chamber, an inlet port and two or more mixing chambers. It is unclear whether the "two or the two or more mixing chambers" refers to the two or more mixing chambers recited in claim 4, or whether other mixing chambers are present. It is vague as to whether one conduit provides fluid communication between two or more mixing chambers, or whether more than one conduit is present for fluid communication.

Claim 9 recites "a mixing chamber", and it is unclear whether the recited mixing chamber is the same as the "at least one mixing chamber" or "the one or more mixing chambers" recited in claim 1. It is vague as to whether the device comprises a further mixing chamber different from that recited in claim 1.

With respect to claim 12, it is unclear whether the low or non birefringent glass walls are located in the mixing chamber or the detection chamber. The walls are recited as delineating two or more of the detection chamber walls in claim 1, but in claim 12, the walls are recited as being

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located in the mixing chamber. It is unclear whether the low or non birefringent glass walls are located in the mixing chamber or the detection chamber. Furthermore, it is unclear whether the mixing chamber and detection chamber are meant to be the same chamber. For the purposes of this Office Action, the Examiner assumes that the mixing and detection chambers are separate, and the detection chamber contains the low or non birefringent glass that has microgrooves.

Claim 14 recites the limitation "the flow pattern" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 14 also recites "the one or more mixing chambers", which is vague because it is unclear whether the one or more mixing chambers are the same as the at least one mixing chamber recited in claim 1 or if the device further comprises additional mixing chambers.

Regarding claim 17, part (a) recites "at least one assay cassette". Line 2 of claim 2 recites the device comprising a cassette. It is unclear whether the at least one assay cassette recited in claim 17 is the same as the cassette in claim 1 or whether the device comprises assay cassettes in addition to the assay cassette of claim 1.

With respect to claims 19 and 20, it is unclear how the filter and reader are in communication with the detection chamber. It is vague as to whether the reader and filter are incorporated into the detection chamber or whether the reader and filter are outside of the chamber.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-6, 9-11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US 6,302,134) in view of Hajduk et al. (US 6,836,326).

Kellogg et al. teach a device for detecting the presence of a ligand in a sample comprising: a cassette having a first and second end (cassette is in the form of a disk wherein the first end is at the center of the disk and the second end is at the edge of the disk, Fig. 1), and comprising an inlet port at the first end which is in fluid communication with at least one flow channel (901, Fig. 26; col. 7, lines 35-37; col. 10, lines 36-40), the flow channel comprising: in series, at least one mixing chamber (605, Fig. 15A; col. 29, lines 2-8 and 15-25) and a detection chamber in fluid communication with the at least one mixing chamber (mixed fluid from mixing chamber travels to mixed fluid receiving chamber, which can contain detection means, and the elements are therefore in fluid communication, 606, Fig. 15A; col. 27, lines 27-41); wherein the detection chamber is located at the second end of the cassette (Fig. 28, detection chamber is at the bottom of the device); and the arrangement of an outlet port (waste reservoir, Fig. 26, 905; col. 29, line 1), one or more mixing chambers and detection chambers define a substantially

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linear flow path from the first end to the second end of the cassette (arrangement is linear; Fig. 28). Kellogg et al. fail to teach a detection chamber comprising low or nonbirefringent glass.

Hajduk et al. teach detection chambers delineated on at least two sides by nonbirefringent glass (a vial surrounds the sample on more than two sides, col. 2, lines 22-27), in order to avoid alteration of polarization characteristics of light passing through the chamber.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Kellogg et al., a detection chamber delineated by nonbirefringent glass as taught by Hajduk et al., in order to provide rapid screening and characterization of an array of compounds or materials.

Regarding claims 2-5, Kellogg et al. teach an inlet port comprising a one-way valve (capillary junction; col. 11, lines 27-32; col. 11, lines 27-33; col. 26, lines 40-44). Kellogg et al. also teach a first conduit connecting the inlet port and the mixing chamber (fluid flows through entry port and into mixing chamber when valve is released; col. 26, lines 40-44), and a second conduit connecting the mixing chamber and the detection chamber (detection chamber is mixed fluid receiving reservoir; col. 27, lines 20-24). Kellogg et al. further teach the flow channel comprising two or more mixing chambers arranged in series, wherein the first mixing chamber is in fluid communication with an inlet port, and wherein the last mixing chamber is in fluid communication with the detection chamber (mixed fluid receiving reservoir, col. 26, line 53-col. 27, line 26), and the flow channel comprising two or more conduits wherein each conduit is arranged in series with the inlet port, the mixing chambers, and the detection chamber, and a conduit is in fluid communication with the inlet port and a mixing chamber (col. 26, line 53-col. 27, line 26).

With respect to claims 6 and 9-11, Kellogg et al. teach one or more conduits comprising structures that induce turbulent flow (col. 27, lines 1-7). The structures that induce turbulent flow are flat plates in the mixing chamber, which are baffles and are non-moving (col. 22, lines 38-59). Kellogg et al. further teach a conduit situated between the mixing chamber and the detection chamber that induces laminar flow (col. 22, lines 45-47; col. 23, lines 9-12). Kellogg et al. also teach the conduit having an internal diameter that is greater than the internal diameter of the mixing chamber (col. 22, lines 27-37) and one or more of the mixing chambers comprising structures that induce turbulent flow (col. 22, lines 38-57).

With respect to claims 13, 19 and 20, Hajduk et al. teach a polarized filter in communication with a detection chamber and adjacent to a wall of nonbirefringent glass (col. 5, lines 40-44), in order to achieve rapid screening. Hajduk et al. also teach a reader capable of detecting light transmission through the detection chamber from a light source applied to the first side of the detection chamber (col. 2, lines 15-18 and 49-63).

Claim 14 does not appear to provide any further product limitations to provide for turbulent and laminar flow within the flow channel. Therefore the device of Kellogg et al. is capable of providing turbulent flow between the inlet port and the mixing chamber and laminar flow between the outlet port and the mixing chamber.

With respect to claims 15, 16 and 18, Kellogg et al. teach the cassette comprising an array of multiplicity of channels (col. 10, lines 7-19), a multiplicity of channels encompasses at least two channels and includes the recited two to fifty flow channels

Regarding claim 17, Kellogg et al. teach the cassette further comprising a flow directing device in communication with the cassette, which interfaces with at least one assay to initiate and

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direct flow of fluid through a flow channel along a substantially linear path from the first end to the second end of the at least one assay cassette (electromagnetic means to provide rotation of the disk; col. 6, lines 23-44).

4. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US 6,302,134) in view of Stearns (US 2,645,463).

Kellogg et al., as applied to claims 1 and 4-6, teach a device comprising conduits that induce turbulent flow, but fail to teach structures that induce turbulent flow.

Stearns teaches a conduit comprising non-moving baffle structures that induce turbulent flow (15, Fig. 3; col. 3, lines 27-40), in order to provide turbulent flow before addition of a third fluid.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the conduits of the device of Kellogg et al., non-moving baffle structures that induce turbulent flow as taught by Stearns, in order to ensure homogeneous mixing of fluids in a conduit.

5. Claims 1, 17, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4,673,657) in view of Hajduk et al. (US 6,836,326).

Christian teaches a device for detecting the presence of a ligand in a sample comprising: a cassette having a first and second end, and comprising an inlet port at the first end which is in fluid communication with at least one flow channel (84', Fig. 18; col. 15, lines 42-48), the flow channel comprising: in series, at least one mixing chamber (sample mixes with reagents as it passes through chambers: 70', 66', 65', Fig. 18; col. 16, lines 22-35) and a detection chamber in fluid communication with the at least one mixing chamber (col. 17, lines 41-45; col. 18, line 66-

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col. 19, line 5; Fig. 17); wherein the detection chamber is located at the second end of the cassette (second system is added at the end of the first system to provide detection, therefore detection chamber is at second end of cassette, col. 17, lines 40-45; Fig. 17); and the arrangement of an outlet port, one or more mixing chambers and detection chambers define a substantially linear flow path from the first end to the second end of the cassette (chambers are arranged linearly; Fig. 16). Kellogg et al. fail to teach a detection chamber comprising low or nonbirefringent glass.

Hajduk et al. teach detection chambers delineated on at least two sides by nonbirefringent glass (vials, col. 2, lines 22-27), in order to avoid alteration of polarization characteristics of light passing through the chamber.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Christian et al., a detection chamber delineated by nonbirefringent glass as taught by Hajduk et al., in order to provide rapid screening and characterization of an array of compounds or materials.

Regarding claims 17, 21 and 22, Christian teaches a flow directing device in communication with the assay cassette, wherein the flow directing device interfaces with at least one assay cassette to initiate and direct the flow of fluid through the at least one flow channel along a linear path from the first end to the second end of the cassette (col. 15, line 39-col. 16, line 68). Christian further teaches the flow directing device being a roller that contacts the first end of the at least one assay cassette and rolls over the length of the array of channels thereby providing pressure that induces fluid flow along the length of the cassette toward the second end of the cassette (col. 15, line 39-col. 16, line 68).

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6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. in view of Hajduk et al. as applied to claim 1 above, and further in view of Murphy et al. (US 5,864,641).

Kellogg et al. in view of Hajduk et al. teach a device comprising non birefringent glass, but fail to teach the low or non birefringent glass walls having longitudinal microgrooves.

Murphy et al. teach long period gratings in non birefringent glass, which form longitudinal microgrooves (col. 4, line 63-col. 5, line 2; col. 2, lines 6-26), in order to generate significantly larger signal-to-noise ratio.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Kellogg et al. in view of Hajduk et al., longitudinal microgrooves in the non birefringent glass as taught by Murphy et al., in order to provide increased detection accuracy.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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